



66307-374-7

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|-----------------------------------|-------------------------|
| In re Application of: |) PATENT |
| Andrew CHILDS et al. |) |
| |) GROUP: 1796 |
| Serial No.: 10/590,668 |) |
| |) EXAMINER: Wang, C. C. |
| Filed: March 6, 2007 |) |
| |) CUSTOMER NO.: 25269 |
| |) |
| POLYAPHRON DISPERSIONS CONTAINING |) CONFIRMATION NO. 3787 |
| A COMPLEX INTERNAL PHASE |) |

DECLARATION UNDER 37 C.F.R. 1.132

I, Nigel Crutchley, who am a citizen of the United Kingdom, residing at 36 Recreation Road, Guildford, Surrey, GU1 1HP, United Kingdom, hereby declare and state as follows.

Academic Background

1. From 1995 to 1998 I attended the Royal Holloway College of the University of London, located in London, United Kingdom, and graduated with a Degree in Biology.

2. From 2002 to 2006 I attended the University of Leeds, located in Leeds, United Kingdom, and graduated with a Doctorate in Colour and Polymer Chemistry.

Employment History

3. From 1998 to 2000 I worked for Cabi Bioscience as a laboratory technician.

4. From 2000 to 2002 I worked for Disperse Technologies Ltd., located in Leatherhead, Surrey, United Kingdom, as a Scientist.

5. From 2007 to date I have worked for Drug Delivery Solutions Ltd., located in Leatherhead, Surrey, United Kingdom, as a Senior Scientist/Research Scientist.

6. I have worked with dispersion systems in my employments since 2000.

Reason for Experimentation

7. I have read the above-identified patent application and its prosecution history, including the Office Action of April 28, 2009 wherein the examiner has rejected claims 1-9 and 11-13 as being unpatentable over Fukuda (U.S. Patent No. 4,254,105) and claim 10 as being unpatentable over Fukuda in view of Barnett et al. (U.S. Patent No. 4,999,198).

8. I have conducted the following experimentation to demonstrate the unobvious nature of the invention claimed in the above-identified patent application relative to Fukuda.

Experimental Procedure

Experiment 1 (based on Fukuda example 11) – 40% Internal Phase

Part A: Water in oil formulation

| | |
|---------------------|--------------|
| Liquid paraffin | 28.5 |
| Olive oil | 18.0 (15.0)* |
| Sunscreen agent | - (3.0)* |
| Sorbitan monooleate | 3.0 |
| Glucose | 1.5 |
| Water | 49.0 |
| Total | 100.0 |

* The unknown "sunscreen agent" was replaced by an increase in the olive oil component.

The water in oil system was made by adding the water/glucose component to the premixed oil phase whilst being mixed with a

homogenizer device (Ultra-Turrax T25 made by Janke & Kunkel) at 13500 rpm. Rate of addition was spaced over a 15 minute period. Fukuda does not give any details of the homogenizer he used or speed settings.

The system made a stable dispersion with the water droplets $\approx 1\mu\text{m}$ as seen under a light microscope.

Part B: Complex emulsion

| | |
|-------------------------------|-------|
| Water in oil emulsion (above) | 40.0 |
| Polysorbate 60 | 0.2 |
| Water | 59.8 |
| Total | 100.0 |

The complex emulsion was made by addition of the water in oil emulsion into the premixed surfactant/water phase. The addition was carried out over 5 minutes whilst being stirred using the homogenizer at 8000 rpm (minimum setting). Fukuda describes using the homogenizer to gently emulsify the water in oil emulsion into the second aqueous phase to make the water in oil in water multiple emulsion.

The complex emulsion made and appears stable. The system will easily dilute within water showing that the continuous phase remains aqueous.

Experiment 2 (based on Fukuda example 11) – 50% Internal phase

Part A: Water in oil Formulation

Prepared exactly as above (Experiment 1, Part A).

Part B: Complex emulsion

| | |
|-------------------------------|-------|
| Water in oil emulsion (above) | 50.0 |
| Polysorbate 60 | 0.2 |
| Water | 49.8 |
| Total | 100.0 |


Same production methodology as used in Experiment 1. Towards the end of the production it was noticed that the viscosity increased significantly before subsequently thinning. On completion the system appears to have at least partially inverted. The system can not be readily diluted with water and evidence of bulk oil is present on the surface.

Conclusions

9. Based on the foregoing experimental results, it can be seen that if the internal W/O content in the W/O/W emulsion of Example 11 in Fukuda is raised to 50 wt%, the lotion is not stable. As such, I do not believe it would be obvious to increase the W/O internal phase content in Fukuda to 50 wt% or higher. I note that claim 11 in the above-identified patent application defines a content of internal phase (when both the first and second phases thereof are liquids at room temperature) of 70-95 wt%.

I further more declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section

1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Nigel Crutchley

26/10/09
Date